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10/582,982	06/15/2006	Robert C. Shipman	13516-4	1560

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Attachment to Advisory

Continuation of box 3: The amendments filed on 8/28/2009 include new claims 86-89, and have not canceled a corresponding number of finally rejected claims. The addition of these new claims would require further search and consideration.

The interview records are complete as the applicants have presented their view of the interviews of record.

The arguments to the presentation of new claims are not persuasive as the amendment has added new claims and has not canceled a corresponding number of claims. The examiner has indicated that amendment of the claims to require additional probes or SEQ ID NO is not precluded by the restriction requirement as the instant case is the national stage entry of a PCT and thus follows lack of unity practices. Finally as noted previously the lack of unity and rejection of the claims is drawn to the open (comprising) language which allows for inclusion of additional sequences which broadly encompasses probes to all 48 known ABC family transporter genes. Amendment of the independent claims to be limited to a specific combination of less than 48 ABC transporter genes by closed (consisting of) language would overcome the art of record as there appears to be no suggestion to select a combination of less than all the genes other than those taught by Denefle.

Continuation of box 11:

The response asserts that the references provide no motivation to make an array as claimed.

The response continues on page 9 by asserting the Denefle is drawn to detecting polymorphisms and provides no motivation or suggestion of detecting gene expression as the specification intends the claimed invention to be used. These arguments have been thoroughly reviewed but are not considered persuasive as the claims are drawn to a product of an array and thus are examined by their structural features not their intended use as asserted. Further, Denefle teaches on page 50 determination of expression of ABCA9, ABCA5, and ABCA6. Thus Denefle does teach and or suggest detection of expression.

The response continues by asserting that Denefle's only reference to a kit comprising multiple probes which comprise a full length sequence or a fragment thereof and asserts this does not provide motivation for the claimed array. These arguments have been thoroughly reviewed but are not considered persuasive as Denefle teaches, "According to a specific embodiment of the detection kit described above, such a kit will comprise a plurality of oligonucleotide probes and/or primers in accordance with the invention which may be used to detect a target nucleic acid of interest or alternatively to detect mutations in the coding regions or the non-coding regions of the nucleic acids according to the invention, more particularly of nucleic acids comprising any one of SEQ ID NOs: 1-4 and 9-126, or a complementary nucleotide sequence. Thus, the probes according to the invention, immobilized on a support, may be ordered into matrices such as "DNA chips". Such ordered matrices have in particular been described in US patent No. 5,143,854, in published PCT applications WO 90/15070 and WO 92/10092. Support matrices on which oligonucleotide probes have been immobilized at a high

density are for example described in US patent No. 5,412,087 and in published PCT application WO 95/11995." (bottom page 68-top page 69). Further Denefle teaches the probes of the invention can be used to detect target nucleic acids (page 70, lines 25-27). Thus Denefle envisions DNA chips or microarrays for the detection of nucleic acids, which would include detection of mRNA or DNA.

The response continues by asserting that Denefle makes no mention of gene expression. This argument has been thoroughly reviewed but is not considered persuasive as Denefle on page 67 teaches the probes of the instant invention can be used to detect messenger RNA, which is expression analysis.

The response continues by asserting that Dean does not teach or discuss gene expression. Again it is noted that the instant claims are not drawn to gene expression, but an array. The teachings of Dean are presented to further demonstrate that ABC transporter gene family was known. Further the teachings of Dean that the ABC transporter genes are involved in many diseases and pathological conditions providing motivation for one of skill in the art to make an array to detect known members of the gene family. Contrary to the assertion of the response, Dean teaches, "analysis of ABC gene expression combined with gene disruptions should yield important clues to gene function." Thus Dean does suggest gene expression.

The response continues by asserting that full length sequences do not render the claimed probes obvious. The response begins by admitting that a full length sequence can render a probe obvious. It is noted that claim 49 as presented requires 2 probes in a microarray comprising and sequences that "have" a sequence "consisting of." The

use of the broad "have" followed by the narrow "consisting of" results in a broad claim interpretation. The response begins by presenting the teachings of Ex parte Bandman, which is a non-precedential decision of the board of appeals as to the obviousness rejection of a method claim. The reliance on this and other non-precedential decisions by the board of appeals are inappropriate as they are not precedential and thus are do not set precedent for examination or the appeal process.

The response then moves to the decision of Kolberg, again another non-precedential decisions of the Board of appeals. The reliance on this and other non-precedential decisions by the board of appeals are inappropriate as they are not precedential and thus are do not set precedent for examination or the appeal process.

The response then argues in Re O'Farrell and Kubin. These arguments have been thoroughly reviewed but are not considered persuasive as the Denefle teaches probes that would function to allow detection of ABC transporter genes as the response asserts is the intended use of the claimed invention. Further the examiner has provided specific sequences and motivation to combine them in an array. There is no evidenced that the combined teachings result in anything more then the predictable use of prior art elements according to their established function.

The response continues by asserting the office action provides no particular recognition of the significance of the claimed sequences and no suggestion to design probes based thereon. These arguments have been thoroughly reviewed but are not considered persuasive as the claimed sequences are ABC transporter gene and the art of record suggests detection of such sequences. The art of Denefle and Dean both

suggest gene expression analysis of the family of genes; thus rendering the claimed arrays obvious.

The response continues by asserting the artisan would merely be throwing metaphoric darts at the prior art possibilities. These arguments have been thoroughly reviewed but are not considered persuasive as the teachings of the prior art clearly indicate that there are 48 known ABC transporter genes with known sequences. Thus there are a finite number of possibilities with a reasonable expectation of success as one of skill in the art would be able predictably design probes to known sequences.

The response continues by asserting that the full length is not functional equivalents of the claimed probes. The response asserts that there is no evidence that the full length prior art sequences allow for identification of a single ABC transporter gene out of the family of at least 47 known ABC transporter genes. These arguments have been thoroughly reviewed but are not found persuasive as the claims do not require the detection of a single sequence. Claim 49 is drawn to an array of nucleic acid comprising sequences. It is noted that claim 49 as presented requires 2 probes in a microarray comprising and sequences that "have" a sequence "consisting of." The use of the broad "have" followed by the narrow "consisting of" results in a broad claim interpretation. The response further asserts that the full length sequences would not be suitable for use as such probes on array because their length (thousands or tens of thousands of nucleotide bases) and likely have homology. This argument has been thoroughly reviewed but is not considered persuasive as it is within the skill of the art to

select probes from members of a gene family by aligning them and selecting unique regions for probe design.

The response then presents the teachings of Ex parte Weichselbaum as to the combination of a promoter and a therapeutic protein. The reliance on this and other non-precedential decisions by the board of appeals are inappropriate as they are not precedential and thus are do not set precedent for examination or the appeal process.

The response then presents arguments to 2144.06 to equivalents known for the same purpose and cites, " In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents." 2144.06 continue to place this statement in context by teaching, "The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components." The instant rejection is not based on the presence of the nucleotide sequences in a Markush group, but determination that the sequences were known and part of a known gene family and methods of making probes was known, absent secondary considerations.

The response then jumps to 716.02(e) noting that in a declaration applicant is not required to compare the prior art if no such prior art exist. The examiner concurs, but no such requirement has been made. Applicant's have asserted in the declaration filed by Dr. Shipman than the claimed array and probes are better then the instant combination of the prior art of record, but has provided no evidence of such unexpected

results or improved properties, but merely an bio-informatics analysis. The claims are drawn to a composition and not a method of probe design. The response then reiterates arguments to the declaration by Dr. Shipman based on bioinformatics analysis of nucleic acid sequences that have been previously address and are drawn to bioinformatics analysis of sequences and do not provide that the claimed array and probes have an unexpected result over the prior art of record. The response asserts that the data obtained indicate the claimed probes would be better at identifying the targets under stringent conditions then comparative probes. The declaration has provided no experimental evidence that the claimed probes function as probes any better then probes that are obvious over the prior art of record. Further the declaration is limited to a single bioinformatics approach that is designed for primer design, while numerous other software options were available as Andronescu (Nucleic Acid Research (2003) volume 31, pages 3416-3422) discloses RNAsoft; Winer et al (Analytical Biochemistry (1999) volume 270, pages 41-49) discloses oligo V; and Bustin (Journal of Molecular Endocrinology (2002) volume 29, pages 23-9) discloses Primer3, JAMBW, NCBI BLAST, and molecular beacons software. The teachings of Andronescu, Winer and Bustin are not to be construed as part of the instant rejection but are presented in response to arguments and demonstrate that one of skill in the art at the time would have the ability to use these software options.

The response continues by bringing arguments to motivation to attempt to make the claimed arrays. As addressed above Denefle suggests microarray for detection of

messenger RNA and Dean specifically suggests expression analysis of ABC transporter genes.

The response concludes by asserting the examiner has used unsupported musing and asserts the examiner has not considered rebuttal argument as required by 2145. These arguments have been thoroughly reviewed but are not considered persuasive as the MPEP 2145 also requires, “the evidence must be reasonably commensurate in scope with the claimed invention.” The evidenced presented does not demonstrate the probes give an unexpected result. The declaration merely demonstrates that a single bioinformatics approach did not result in the same probes. The bioinformatics may suggest probes, but even the declaration states, “In all cases, sequences selected using computer programs need to be verified and validated and in almost all cases, the experience, knowledge and skill of a senior scientist is required to obtain a sequence that, when reduced to practice, provides the desired probe product and performance in gene expression analyses." Thus the examiner by applicants own declaration has demonstrated that one of skill in the art could determine which probes would or would not work, thus giving the artisan a reasonable expectation of success.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-:4:30, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert